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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,732	07/28/2003	Kiyoshi Kasai	240905US0	3797

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EXAMINER	
YANG, NELSON C	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/627,732	KASAI ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *3-5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. In light of applicant's arguments on January 12, 2007 with respect to the species election on December 14, 2006 that all three limitations in the recitation of at least one of (1), (2), and (3) is as follows: (1) said radically polymerizable vinyl monomer is at least one polymerizable unsaturated carboxylic acid selected from the group consisting of acrylic acid, methacrylic acid, propionic acid, itaconic acid, fumaric acid, maleic acid, maleic anhydride, 2-carboxyethyl acrylate, and a 2-carboxyethyl acrylate oligomer; (2) said radically polymerizable vinyl monomer having a strong acid group is present and is at least one radically polymerizable monomer having a strong acid selected from the group consisting of styrenesulfonic acid, 2-sulfoethyl methacrylate, 2-acrylamido-2-methylpropanesulfonic acid, and 1-allyoxy-2-hydroxypropanesulfonate, or sodium salt thereof, a potassium salt thereof, or an ammonium salt thereof; (3) said radically polymerizable vinyl monomer copolymerizable with the monomers (1) and (2) is at least one radically polymerizable vinyl monomer selected from the group consisting of an aromatic vinyl compound, an acrylate, a methacrylate, a vinyl ester compound, a polymerizable double bond-containing cyan compound, and a polymerizable double bond-containing compound" are in fact required, the species election has been withdrawn.

Claim Objections

2. Claims 6, 8, 9, 12, 13, 15, 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous

claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In applicant's arguments with respect to the restriction requirement, applicant's argued that all three of the conditions in the limitation "at least one of (1), (2), and (3) is as follows: (1) said radically polymerizable vinyl monomer is at least one polymerizable unsaturated carboxylic acid selected from the group consisting of acrylic acid, methacrylic acid, propionic acid, itaconic acid, fumaric acid, maleic acid, maleic anhydride, 2-carboxyethyl acrylate, and a 2-carboxyethyl acrylate oligomer; (2) said radically polymerizable vinyl monomer having a strong acid group is present and is at least one radically polymerizable monomer having a strong acid selected from the group consisting of styrenesulfonic acid, 2-sulfoethyl methacrylate, 2-acrylamido-2-methylpropanesulfonic acid, and 1-allyoxy-2-hydroxypropanesulfonate, or sodium salt thereof, a potassium salt thereof, or an ammonium salt thereof; (3) said radically polymerizable vinyl monomer copolymerizable with the monomers (1) and (2) is at least one radically polymerizable vinyl monomer selected from the group consisting of an aromatic vinyl compound, an acrylate, a methacrylate, a vinyl ester compound, a polymerizable double bond-containing cyan compound, and a polymerizable double bond-containing compound" were required, rendering the dependent claims moot, as they do not further limit the parent claim.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 6-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation 1) 0.1 to 20% by weight of a radically polymerizable vinyl monomer having a carboxylic group, (2) 0.05 to 20% by weight of at least one of a radically polymerizable vinyl monomer having a strong acid group and a compound represented by the following formula (I):CH.sub.2.dbd.C(R.sup.1)CO(OCH.sub.2CH.sub.2).sub.nOR.sup.2 (I)wherein R.sup.1 represents a hydrogen atom or a methyl group, R.sup.2 represents a hydrogen atom, a C.sub.1 to C.sub.6 alkyl group, an alkoxyphenyl group, a phenyl group, an acryloyl group, or a methacryloyl group, and n represents a number of 2 to 22, or combinations thereof, and (3) 60 to 99.8% by weight of a radically polymerizable vinyl

monomer copolymerizable with the monomers (1) and (2), and the claim also recites "(1) said radically polymerizable vinyl monomer is at least one polymerizable unsaturated carboxylic acid selected from the group consisting of acrylic acid, methacrylic acid, propionic acid, itaconic acid, fumaric acid, maleic acid, maleic anhydride, 2-carboxyethyl acrylate, and a 2-carboxyethyl acrylate oligomer; (2) said radically polymerizable vinyl monomer having a strong acid group is present and is at least one radically polymerizable monomer having a strong acid selected from the group consisting of styrenesulfonic acid, 2-sulfoethyl methacrylate, 2-acrylamido-2-methylpropanesulfonic acid, and 1-allyoxy-2-hydroxypropanesulfonate, or sodium salt thereof, a potassium salt thereof, or an ammonium salt thereof; (3) said radically polymerizable vinyl monomer copolymerizable with the monomers (1) and (2) is at least one radically polymerizable vinyl monomer selected from the group consisting of an aromatic vinyl compound, an acrylate, a methacrylate, a vinyl ester compound, a polymerizable double bond-containing cyan compound, and a polymerizable double bond-containing compound" which is the narrower statement of the range/limitation.

6. Claim 1 recites "at least one of (1), (2), and (3) is as follows: (1) said radically polymerizable vinyl monomer is at least one polymerizable unsaturated carboxylic acid selected from the group consisting of acrylic acid, methacrylic acid, propionic acid, itaconic acid, fumaric acid, maleic acid, maleic anhydride, 2-carboxyethyl acrylate, and a 2-carboxyethyl acrylate oligomer; (2) said radically polymerizable vinyl monomer having a strong acid group is present and is at least one radically polymerizable monomer having a strong acid selected from the group consisting of styrenesulfonic acid, 2-sulfoethyl methacrylate, 2-acrylamido-2-methylpropanesulfonic acid, and 1-allyoxy-2-

hydroxypropanesulfonate, or sodium salt thereof, a potassium salt thereof, or an ammonium salt thereof; (3) said radically polymerizable vinyl monomer copolymerizable with the monomers (1) and (2) is at least one radically polymerizable vinyl monomer selected from the group consisting of an aromatic vinyl compound, an acrylate, a methacrylate, a vinyl ester compound, a polymerizable double bond-containing cyan compound, and a polymerizable double bond-containing compound." However, applicant argues that all three limitations are required by the claim, rendering the claim ambiguous as to which recitations of (1), (2), and (3) are in fact required, and which are not.

7. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 2, 6-20, 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Steckler [US 4,036,788].

With respect to claim 1, Steckler teaches hydrogels comprising acrylic acid (component (1)) or styrene sulfonic acid (component (2)) (column 4, lines 35-53) at a concentration of 50% to 0.05% (column 10, lines 15-28), a compound with the formula $CH_2=C(R^1)CO(OCH_2CH_2)_nOR^2$ (column 7, lines 15-30) at a concentration of 0.2% to 12% (component (2)) (column 10, lines 15-28), and N-vinyl imidazole (polymerizable double bond containing compound) (column 3, lines 53-65) at a concentration of 20% to 90% (component (3)) (column 10, lines 15-28). Streckler teaches that the hydrogels may be ground into particles such as a powder (column 11, lines 25-30) or rods (column 11, lines 65-67). Streckler et al further teach that hydrogels may be complexed with biologically active materials such as chemicals, basic drugs and other pharmaceuticals, hormones, enzymes (column 14, lines 29-57).

It is noted that claim 1 is a product by process claim, reciting a way of forming a support polymer by radical emulsion polymerization of a composition. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, since the polymerization of the composition taught by Streckler would result in the same polymers as the polymerization of the composition recited in claim 1, Streckler anticipates the claim.

11. With respect to claim 2, Steckler teaches hydrogels comprising a styrene sulfonic acid (p-vinyl-benzenesulfonic acid) (column 4, lines 49-55, claim 1).

12. With respect to claim 6, Steckler teaches hydrogels comprising acrylate and methacrylate (column 8, lines 50-55) at 0% to 50% (column 4, lines 35-53).

13. Since claim 1 recites a product formed by radical emulsion polymerization of a composition comprising acrylic acid, the resulting product formed using acrylate or methacrylate would be the same. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

14. With respect to claims 7-8, 11, 12, 18 Steckler teaches hydrogels comprising styrene sulfonic acid (column 4, lines 35-53) at a concentration of 50% to 0.05% (column 10, lines 15-28), a compound with the formula $CH_2=C(R^1)CO(OCH_2CH_2)_nOR^2$ (column 7, lines 15-30) at a concentration of 0.2% to 12% (column 10, lines 15-28).

15. With respect to claims 9, 13, 15, Streckler teaches N-vinyl imidazole (aromatic vinyl compound and double bond-containing compound) (column 3, lines 53-65) at a concentration of 20% to 90% (column 10, lines 15-28).

16. With respect to claims 10, 14, 16, 19, Streckler teaches that the hydrogel may comprise a combination of methacrylate (column 9, lines 10-20) at a concentration of 0% to 50% and ethyl vinyl ether (column 9, lines 35-45) at a concentration of 0% to 30% (column 10, lines 15-30).

17. With respect to claim 17, Steckler teaches hydrogels comprising acrylic acid or styrene sulfonic acid (column 4, lines 35-53) at a concentration of 50% to 0.05% (component (1) and part of component (2)) (column 10, lines 15-28), a compound with the formula $CH_2=C(R^1)CO(OCH_2CH_2)_nOR^2$ (column 7, lines 15-30) at a concentration of 0.2% to 12% (component (2)) (column 10, lines 15-28), and a hydroxymethacrylate (column 8, lines 50-55) at 0% to 50% and N-vinyl imidazole (polymerizable double bond containing compound) (column 3, lines 53-65) at a concentration of 20% to 90% (component (3)) (column 10, lines 15-28). Streckler teaches that the hydrogels may be ground into particles such as a powder (column 11, lines 25-30) or rods (column 11, lines 65-67). Streckler et al further teach that hydrogels may be complexed with biologically active materials such as chemicals, basic drugs and other pharmaceuticals, hormones, enzymes (column 14, lines 29-57).

18. With respect to claim 20, Streckler teaches the presence of polymerization catalysts (column 10, lines 50-60).

19. With respect to claim 22, Streckler teaches the hydrogels are combined with enzymes, which is a protein (abstract).

20. Claims 21, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steckler [US 4,036,788].

Steckler teaches hydrogels comprising acrylic acid (component (1)) or styrene sulfonic acid (component (2)) (column 4, lines 35-53) at a concentration of 50% to 0.05% (column 10, lines 15-28), a compound with the formula $CH_2=C(R^1)CO(OCH_2CH_2)_nOR^2$ (column 7, lines 15-30) at a concentration of 0.2% to 12% (component (2)) (column 10,

lines 15-28), and N-vinyl imidazole (polymerizable double bond containing compound) (column 3, lines 53-65) at a concentration of 20% to 90% (component (3)) (column 10, lines 15-28). Streckler teaches that the hydrogels may be ground into particles such as a powder (column 11, lines 25-30) or rods (column 11, lines 65-67). Streckler et al further teach that hydrogels may be complexed with biologically active materials such as chemicals, basic drugs and other pharmaceuticals, hormones, enzymes (column 14, lines 29-57). Streckler further teaches the hydrogels are combined with enzymes, which is a protein (abstract). Streckler does not teach that the particle size ranges from 0.03 to 2 μm or that the amount of the physiologically active substance ranges from 5 to 80 mg per 1 g of the particles.

Although Streckler does not teach that the particle size ranges from 0.03 to 2 μm or that the amount of the physiologically active substance ranges from 5 to 80 mg per 1 g of the particles, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, one of ordinary skill in the art at the time of the invention would have found it obvious to have had particle with sizes ranging from 0.03 to 2 μm and physiologically active substance ranging from 5 to 80 mg per 1 g of the particles,

Response to Arguments

21. Applicant's arguments filed September 26, 2006 have been fully considered but they are not persuasive. In particular, it is noted that claim 1 appears to be a product by process claim. "[E]ven though product-by-process claims are limited by and defined by

the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since applicant has not disclosed how the resulting polymer formed from the composition recited in claim 1 would differ from the polymer disclosed by Streckler, applicant's arguments are not found persuasive.

Conclusion

22. No claims are allowed.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
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